

Suggested Guidance about IPA Reviews (Third Draft)

California's Information Practices Act (IPA) specifies certain minimum criteria that CPHS must consider when reviewing research applications under provisions of the IPA. In addition, CPHS may elect to consider additional factors related to data privacy and security for certain projects. This may occur when one or more of the following circumstances apply for a specific project, or for other reasons related to the particular protocol, at the reviewer's and CPHS's discretion:

- The requested data includes especially sensitive information about physical health, including but not limited to variables related to abortion, gender-affirming care, genetic testing, or HIV/AIDS testing.
- The requested data includes especially sensitive information about psychological health, including but not limited to variables related to clinical psychological tests, drug or alcohol abuse, sexual behavior, or suicide.
- The requested data includes especially sensitive social, economic, or legal information, including but not limited to variables related to immigration status, law enforcement or court records, income, or credit history.
- The requested data is for vulnerable populations described in the 2018 Common Rule (45 CFR 46), including but not limited to children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
- The researchers propose to link the requested data to information from other sources that falls within any of the previous descriptions.
- The number or nature of variables that will be available in the data to be analyzed makes re-identification of individuals a possible risk despite researcher efforts to remove identifiers or mask the data.
- The researchers plan to share some or all of the data in a database that will be made available to other individuals not listed on the CPHS application.

Additional factors that CPHS members may elect to consider in IPA reviews of projects described above include but are not limited to:

- Whether consent to use the information for research was obtained when the requested data were originally collected, and if so, whether a reasonable person would be satisfied that their consent could include purposes such as those of the proposed research.
- If no consent was obtained when the data were originally collected, whether the individuals were told that their information would be used for research.
- If the individuals were not told that their information would be used for research, whether a reasonable person would expect that the data collected about them might be used for research.
- Whether a reasonable person would be satisfied that their privacy will be adequately protected by the procedures in the proposed research or would object to having their information used.

- Whether there are particular variables in the proposed project that should not be approved given the risks associated with using them.
- Whether the researchers have provided an expert risk assessment describing the probability that individuals could be re-identified.
- [one committee member believes this is already permitted under the IPA and not needed here] If the researchers propose to remove identifiers and store them separately, whether those identifiers could be completely destroyed at an earlier time instead of retaining them.
- [one committee member believes this is already permitted under the IPA and not needed here] Whether it would be possible to simply not obtain some identifiers that are particularly sensitive and still do the research.
- How long the data for the project will be retained by the researchers.
- Whether the researchers plan to link their data to information from other sources in the future.
- Whether the researchers plan to add additional years of data in the future, either to provide longitudinal information about individuals already in the data or to add information about new individuals.
- How and with whom the data will be shared beyond researchers listed in the CPHS application.